



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

JUN 14 1999 4 09 9 '99 JUN 21 A9 53

Ms. Diane Herron
Director, Regulatory Affairs
Advanced Care Products
Personal Products Company
691 Highway 1
P.O. Box 6024
North Brunswick, New Jersey 08902-0724

Dear Ms. Herron:

This is in response to your letter of June 3, 1999 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Advanced Care Products is making the following claims, among others, for the product **Healthy Woman Soy Menopause Supplement**:

- "reduces hot flashes
- "reduce hot flashes including night sweats
- "helps relieve hot flashes"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate a disease, namely symptomatic disorders of menopause. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

LET 279

Page 2 - Ms. Diane Herron

Please contact us if you require further assistance.

Sincerely,

Lynn A. Larsen, Ph.D.
Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, New Jersey District Office, Office of Compliance, HFR-MA340

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-456 (file)
HFS-450 (r/f, file)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605 (Bowers)
HFV-228 (Benz)
HFV-232 (Brown)
GCF-1 (Dorsey, Nickerson)
f/t:HFS-456:rjm:6/9/99:docname:65472.adv:disc38

**Advanced Care Products**

Personal Products Company
691 Highway 1
P.O. Box 6024
North Brunswick, NJ 08902-0724

June 3, 1999

Dr. Elizabeth Yetley
Director, Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW, Washington, DC 20204

Dear Dr. Yetley:

As per 21 CFR §101.93(a), Advanced Care Products, Personal Products Company (ACP) is making this notification that we are marketing a dietary supplement that bears statements listed in section 403(r)(6) of the Food, Drug and Cosmetic Act.

Name/Address of Distributor:

Advanced Care Products, Personal Products Company
199 Grandview Road
Skillman, NJ 08558

Send Correspondence to:
691 Highway 1 South, P.O. Box 6024
North Brunswick, NJ 08902-6024

Text of Statements being made:

- ◆ soy menopause supplement
- ◆ reduce hot flashes
- ◆ help maintain normal sleep
- ◆ reduce hot flashes including night sweats
- ◆ helps relieve hot flashes

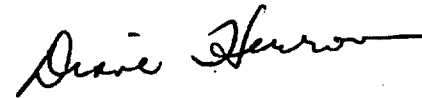
Name of Dietary Supplement:

Healthy Woman Soy Menopause Supplement

June 1, 1999

Please note that our labeling does contain the appropriate disclaimer as required under 21 CFR §101.93(b). Please contact the undersigned at (732) 524-1675 if you have any questions or comments regarding this notification.

Sincerely.

A handwritten signature in cursive script, appearing to read "Diane Herron", followed by a horizontal line.

Diane Herron
Director, Regulatory Affairs